

CLAIMS:

1. A method for measuring low molecular weight heparin concentration on a whole blood sample, comprising:

5 (i) combining a first, whole blood, component of the assay with a second component of the assay to form a resulting mixture, wherein said second component comprises a dry coagulation assay reagent arranged in a substantially flattened configuration and containing magnetic particles distributed substantially homogeneously therethrough and comprising a factor Xa activator, and wherein said resulting mixture is subjected to (ia) an oscillating magnetic field or (ib) a moving permanent magnetic field or (ic) a combination of an oscillating magnetic field and a stationary permanent magnetic field or (id) a rotating magnetic field, whereby said combining of said first component with said second component substantially simultaneously initiates movement of said magnetic particles and a coagulation assay measurement; and

10 15 (ii) monitoring movement induced in said magnetic particles by (ia) or (ib) or (ic) or (id) to obtain said coagulation assay measurement,

wherein said coagulation assay measurement correlates to a concentration of low molecular weight heparin in the whole blood sample.

20 2. The method of claim 1, wherein said whole blood sample is a citrated whole blood sample.

3. The method of claim 1, wherein said magnetic particles are induced to move by applying an oscillating magnetic field thereto.

25 4. The method of claim 1, wherein said magnetic particles are induced to move by applying a moving permanent magnetic field thereto.

5. The method of claim 1, wherein said method is carried out in an element for performing said method, said method comprising adding said first, whole blood, component to said element, wherein said element comprises a channel structure

defining a sample well and a reaction volume in fluid communication with each other, said reaction volume containing said second component, said channel structure having a geometry causing said first, whole blood, component placed in said sample well to be drawn into and filling said reaction volume via capillary action, wherein, after said reaction volume is filled, said first, whole blood, component remains stationary therein.

- 5 6. The method of claim 5, wherein said element further comprises a means for channeling light from an outside source to said reaction volume.
- 10 7. The method of claim 6, further comprising using a means for detecting light scattered or absorbed or reflected from said reaction volume.
- 15 8. The method of claim 7, wherein said element is disposed in sufficiently close proximity to a permanent magnet and to an electromagnet such that said permanent magnet and said electromagnet provide said combination of an oscillating magnetic field and a stationary permanent magnetic field.
- 20 9. The method of claim 8, wherein said element is situated between said permanent magnet and said electromagnet.
10. The method of claim 1, wherein said magnetic particles are induced to move by application of a rotating magnetic field.
- 25 11. The method of claim 1, wherein said Factor Xa activator is Russell's Viper Venom.
12. The method of claim 1, wherein said low molecular weight heparin is enoxaparin.

30

13. A method for measuring low molecular weight heparin concentration on a whole blood sample, comprising:

(i) adding a whole blood sample to a sample well of an element comprising:  
a channel structure defining the sample well and a reaction volume in fluid  
5 communication with each other, wherein said reaction volume is defined by an upper surface having attached thereto a reflectance layer, comprising a semipermeable matrix wherein said reaction volume contains a measured amount of at least one dry coagulation assay reagent arranged in a substantially flattened configuration and containing magnetic particles distributed substantially homogeneously therethrough, wherein a specific volume of said  
10 sample is drawn into said reaction volume by capillary action and contacts, together with said semipermeable layer, said reagent to thereby substantially simultaneously initiate a coagulation assay measurement; and

(ii) performing said coagulation assay measurement by measurement the reflectance of said semipermeable layer,

15 wherein said dry coagulation assay reagent comprises a Factor Xa activator.

14. A kit for measuring low molecular weight heparin concentration on a whole blood sample, comprising, in one or more containers, a permanent magnet, a timing means, and an element containing at least one dry coagulation assay reagent arranged in a substantially flattened format and containing magnetic particles distributed substantially homogeneously therethrough, wherein said at least one dry coagulation assay reagent comprises a Factor Xa activator.

20 15. The kit of claim 14, further comprising a transfer pipette.

25 16. The kit of claim 15, wherein said transfer pipette is made of an essentially nonthrombogenic material, comprises a vented end, is capable of being filled with a liquid sample by capillary action, and is capable of expelling said liquid sample by means of pressure after covering or sealing said vented end.

30 17. A system for measuring low molecular weight heparin concentration on a whole blood sample, comprising:

(i) an instrument with a means for temperature control, a means for producing an oscillating magnetic field or for moving a permanent magnetic field, an illuminating means, and a photometric monitoring means; and

5 (ii) an element for performing said measuring, said element comprising a channel structure defining a sample well and reaction volume in fluid communication with each other, said channel structure having a geometry causing a liquid sample placed in said sample well to be drawn into and filling said reaction volume via capillary action, said reaction volume comprising at least one dry coagulation assay reagent arranged in a substantially flattened configuration and containing magnetic particles distributed substantially homogeneously therethrough, wherein said at least one dry coagulation assay reagent comprises a Factor Xa 10 activator.

18. The system of claim 17, further comprising a transfer pipette.

15 19. The system of claim 18, wherein said transfer pipette is made of an essentially nonthrombogenic material, comprises a vented end, is capable of being filled with a liquid sample by capillary action, and is capable of expelling said liquid sample by means of pressure after covering or sealing said vented end.

20 20. The system of claim 17, wherein said instrument further comprises a heating means comprising a resistive heater strip and a thermistor situated in close proximity to said element.

25 21. The system of claim 17, wherein said element is suitable for performing a whole blood coagulation assay, said channel structure having a geometry causing a blood sample placed in said sample well to be drawn into and filling said reaction volume via capillary action, wherein after said reaction volume is filled, said blood sample remains stationary therein, and wherein said element further comprises an optically or magnetically encodable information means, or both, capable of providing at least one of calibration, quality control, test parameter and patient information.

22. The system of claim 17, wherein said illuminating means includes one or more light sources to illuminate said element and wherein said photometric monitoring means comprises one or more detectors for photometrically monitoring chromogenic or chromomodulating species present in said reaction volume.

23. A system for measuring low molecular weight heparin concentration in a whole blood sample, comprising:

(i) a reaction element comprising (1) a sample well for receiving a liquid sample and (2) a reaction chamber containing a dry coagulation assay reagent arranged in a substantially flattened configuration and in which is embedded, substantially homogeneously therethrough, magnetic particles;

5 (ii) said sample well and said reaction chamber being in fluid communication through a transport zone of geometry such that a volume of liquid sample placed in said sample well and corresponding to the volume of said reaction chamber is transported from said sample well to said reaction chamber simultaneously;

5 (iii) means for optically monitoring said reaction chamber;

10 (iv) means for subjecting said reaction chamber to an oscillating magnetic field;

10 (v) whereby, when said sample is introduced into said reaction chamber, said dry coagulation assay reagent is solubilized and said magnetic particles are thereby freed to move in an oscillating pattern induced by said oscillating magnetic field, thus providing a measurement of the kinetics of said coagulation assay corresponding to changes in the degree of said magnetic particles movement relative to said oscillating magnetic field,

15 wherein said dry coagulation assay reagent comprises a Factor Xa activator.

24. The system of claim 23, further comprising a means for controlling the moment transport of said liquid sample from said sample well to said reaction chamber is initiated.

25. The system of claim 23, further comprising a plurality of reaction chambers in fluid communication with said sample well, and means for transporting a whole blood or plasma sample from one of said plurality of reaction chambers to another of said plurality of reaction chambers.

26. A method for measuring low molecular weight heparin concentration in a whole blood sample, comprising:

25 (i) subjecting to an oscillating magnetic field a reaction element bearing (1) a sample well for receiving a whole blood sample and (2) a reaction chamber containing a dry coagulation assay reagent arranged in a substantially flattened format and in which is embedded, substantially homogeneously therethrough, magnetic particles, said sample well and reaction chamber being in fluid communication through a transport zone of geometry such that a volume of sample placed in said sample well and corresponding to the volume of said reaction chamber is transported from said sample well to said reaction chamber simultaneously;

(ii) adding the whole blood sample susceptible to coagulation to said sample well whereby at least a part of said sample is introduced simultaneously to said reaction chamber, said reagent is solubilized and said particles are freed to move in an oscillating pattern induced by said oscillating magnetic field; and

5 (iii) optically monitoring said reaction chamber to measure kinetics for the coagulation assay corresponding to changes in the degree of said particle movement relative to said magnetic field,

wherein said dry coagulation assay reagent comprises a Factor Xa activator.